The California Performance Review August 27, 2004
c/o Office of Governor Arnold Schwarzenegger
State Capitol
Sacramento, CA 95814

The following comments are being submitted by Evaluation Scientists in the Pesticide Registration Branch of the Department of Pesticide Regulation (DPR), Cal/EPA, regarding recommendations in the California Performance Review (CPR) report which propose to eliminate efficacy data requirements for the registration of pesticides.

Background

The California Department of Pesticide Regulation is responsible for regulating pesticides sold and used within the state. Currently, the registration process includes a detailed scientific evaluation of data to ensure that the pesticide products are safe and effective, and can be used without unacceptable risks to human health and the environment.

As citizens of California and Evaluation Scientists for DPR, we support the need for change in the pesticide registration process. The registration process, as it exists today, has evolved over time. We believe that this process can be further improved and streamlined to facilitate a timely registration of pesticide products with less cost to the registrants, without compromising the protection of human health and the environment.

The Food and Agricultural Code (FAC), section 12824 demonstrates clearly that it is the intention of the legislature for DPR to be charged with the function of ensuring that all pesticides registered for sale and use in California are efficacious for their intended purposes. Furthermore, FAC section 11501 requires DPR to "assure users that pesticides are properly labeled and are appropriate for the use designated by the label." Finally, FAC section 12825 authorizes DPR to cancel the registration of any pesticide "that is of little or no value for the purpose of which it is intended." All of these directives require the review of efficacy data in order for DPR to fulfill these mandates.

CPR Recommendations

The recently completed California Performance Review report stated that DPR's registration processes are primarily to "protect the business interests of data owners, duplicates federal registration processes that already provide adequate protection to data owners, and creates marketplace barriers for pesticide products. This duplication of effort does nothing to improve public health or the environment". The report proposed two recommendations (noted as recommendations A & B) for streamlining DPR's registration process.

Recommendation A

Recommendation A proposes to eliminate the requirement for letters of authorization from the data owners. This would allow the use of submitted data on file at DPR by all parties who submit similar products for registration.

The Evaluation Scientists of DPR fully support Recommendation A in the CPR review. This proposal would eliminate the requirement for letters of authorization in order to utilize any data on file to support product registrations. The letter of authorization allows a pesticide product to be registered in California based upon data which is owned by another company and has been previously submitted to DPR. If the requirement for a letter of authorization were eliminated, the submission and review of most data for products which are similar to currently registered products would no longer be required. The elimination of the need for letters of authorization would dispense with duplicate efficacy data development and review, which would benefit registrants and streamline the review process for these products. Similar savings in costs and review time in addressing most other data requirements would also be realized.

Recommendation B

Recommendation B proposes to eliminate the submission and review of all efficacy data involving agricultural, industrial, and home and garden use pesticides that are not public health-related products. We feel that this recommendation should be modified. It appears that this recommendation is derived from the premise that the U. S. EPA has de-emphasized efficacy data and does not require their submission, and therefore DPR should be consistent with the federal requirement.

In the CPR report, however, DPR is criticized for duplicating the federal registration process without benefiting public health or the environment. Since the review of efficacy data is unique to California, this activity provides direct benefits to the public health, the environment, and the people of California which are not forthcoming as a result of the U.S. EPA registration process.

Some aspects of these benefits are termed “consumer protection” in the CPR report, and dismissed as if this is not a worthy function for DPR. However, consumer protection is still a very important benefit of the registration process, and should not be discarded lightly. The original objective of the pesticide regulatory program which continues today is that products that do not work should not be sold in the state. This principle was the basis for founding the program 100 years ago, and continues to benefit the people of California today.

Resolution

With the implementation of Recommendation A, many of the objections to the requirements for efficacy data disappear. One set of products, those based on old active ingredients, would have no requirements for data generation or payment for letters of authorization, and would also benefit from reduced review times. In addition, DPR is already developing regulations to streamline other aspects of efficacy data requirements and the review process. We would support modifications that would allow utilizing our resources to focus on the evaluation of certain products used in California where efficacy review would be most beneficial. Examples would be new active ingredients, public health products, and other products with unique uses. This would help bring products to market faster while still retaining the benefits of efficacy data review in those areas where it is most productive.

As Evaluation Scientists with DPR, we wish to reiterate our desire to be part of your effort in streamlining the pesticide registration process in California. To that end, we request that you reconsider your recommendation regarding the elimination of most efficacy data requirements. With the implementation of Recommendation A, the registration process will be greatly improved, but will still retain the benefits of the review of efficacy data for certain products containing new active ingredients or with unique uses. Several of these benefits are listed below.

Efficacy data are necessary to establish the correct use rates for pesticide products. The proper rates are important for effective control of targeted pests without causing unnecessary pollution to the environment. Determining the correct use rate is needed for two main reasons: 1) Using rates higher than necessary means more chemical is added to the environment than is needed to do the job, and 2) Ineffective use of pesticides, besides failing to control the pest, would lead to the development of resistance to the pesticide in the target pest. Rates that are too high and excessive applications to control resistant pests translate into added costs and more exposure to pesticides for humans and the environment. Therefore, the evaluation of efficacy data is directly linked to the health and safety of California citizens and the environment.

The market won't police itself. The marketplace does not eliminate ineffective products. Aggressive marketing overcomes the lack of efficacy for new products being introduced into the market. By the time consumers realize that their product of choice is ineffective, many pounds of pesticide may have been added to our environment with no benefit to the user. In addition, any unused portions of the ineffective products may become hazardous waste and require special measures and extra cost for proper disposal. The inability of the marketplace to police the availability of products that do not work is clearly demonstrated by the continued sale of products across the United States which California has found to be non-efficacious. Confirming the efficacy of pesticides, a function which is not conducted at the federal level, is a unique benefit of the pesticide registration process in California.

Elimination of efficacy data review does not save money. The importance of consumer protection for pesticides cannot be overemphasized. The CPR report has identified this responsibility as a negative point. Millions of dollars are spent annually in California on pesticides. If efficacy data review is eliminated, it will cost the people of California more to deal with increased environmental pollution and pest resistance problems from the overuse of ineffective products.

Unique environmental conditions in California. The review of efficacy data generated under California conditions is essential to assessing the performance of pesticides in California. California has unique environmental conditions that vary even within its own regions. These unique environmental conditions cannot be accounted for by federal data requirements alone. It is this uniqueness that contributes to its diversity and production of a wide range of agricultural commodities. Clearly, the determination of pesticide efficacy is a cornerstone to protecting the public health, agriculture, and the environment in California.

California Environmental Quality Act. After revising its regulations and expanding the review of scientific data in 1979, the California pesticide regulatory program was certified to be functionally equivalent to an Environmental Impact Report (EIR), thus satisfying a requirement of the California Environmental Quality Act (CEQA). The certified program included provisions for the review of efficacy data. Elimination of the efficacy data review for pesticide registration could potentially invalidate the CEQA certification as a functionally equivalent program.

Thank you in advance for considering our comments.

Sincerely,

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cc: Terry Tamminen, Secretary Cal/EPA